IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI, Plaintiff, v. NEUROCRINE BIOSCIENCES, INC., Defendant.	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Icahn School of Medicine at Mount Sinai ("Plaintiff" or "Mount Sinai"), by its counsel, and for its complaint against Defendant, Neurocrine Biosciences, Inc. ("Defendant" or "Neurocrine") (collectively, "the Parties"), respectfully states and alleges as follows:

INTRODUCTION AND NATURE OF THE ACTION

1. This is a case about Neurocrine seeking to evade its contractual obligations to obtain permission from, and provide compensation to, Mount Sinai for the ground-breaking research conducted by one of its world-renowned neurologists, Stuart C. Sealfon, M.D. Dr. Sealfon's research was decades in the making and resulted in Mount Sinai's development of ground-breaking, cutting-edge tools to identify, discover, and develop drugs to treat endocrine diseases that, according to Neurocrine, "will provide relief from the pain associated with conditions such [as] endometriosis and uterine fibroids." In other words, Mount Sinai's seminal research serves as the foundation for treatments that will alleviate the severe pain of millions of women who suffer from these and other debilitating endocrine disorders, and related diseases. Neurocrine now seeks to deprive Mount Sinai (and to retain for itself) the rightful compensation that is owed to Mount Sinai for this innovative, medically important research.

2. Mount Sinai licensed Dr. Sealfon's inventions to Neurocrine. This action

concerns Neurocrine's breach of the Parties' license agreement. Mount Sinai is an international leader in medical and scientific training, biomedical research, and patient care. It is the medical school for the Mount Sinai Health System, which includes seven hospital campuses, and has more than 5,000 faculty and nearly 2,000 students, residents, and fellows. Mount Sinai is the home of researchers across thirty-four academic departments and twenty-two multidisciplinary institutes.

3. Mount Sinai is the owner by assignment of patents covering certain inventions made by Mount Sinai researcher Dr. Sealfon that are foundational to the identification, discovery, and development of drug compounds that interact in the human body with receptors for gonadotropin-releasing hormone ("GnRH") and that can be used to treat endocrine diseases and disorders. GnRH plays a key role in the complex cascade of events that lead to sperm maturation in men and ovulation in women, and it is implicated in diseases and disorders including prostate cancer, ovarian cancer, breast cancer, endometriosis, uterine fibroids, prostatic hyperplasia, and precocious puberty. Thus, Mount Sinai's drug discovery tools invented by Dr. Sealfon are foundational in allowing the screening, identification, and development of organic drug compounds that could treat these and other endocrine disorders.

4. Mount Sinai's GnRH technology is the foundation of Neurocrine's GnRH antagonist program to identify drugs for treatment of endocrine disorders, and is the subject of the Parties' 1999 license agreement. Neurocrine deprived Mount Sinai of the value of its foundational GnRH technology by sublicensing that technology to a third party without Mount Sinai's consent in violation of the Parties' express licensing provisions. In so breaching the license agreement, Neurocrine deprived Mount Sinai of its rights to obtain value for the right to sublicense.

The Parties' 1999 License Agreement

5. In the 1998-1999 timeframe, Neurocrine was a small biopharmaceutical company establishing a program to research and develop GnRH antagonists (i.e., drugs that bind to the GnRH receptor ("GnRH-R") to inhibit or decrease a biological response). Neurocrine recognized the need for Mount Sinai's drug discovery tools. On August 27, 1999, Mount Sinai and Neurocrine entered into a license agreement ("License Agreement," attached to this Complaint as Exhibit 1) under which Mount Sinai licensed to Neurocrine the use of Mount Sinai's patent rights covering the foundational Sealfon inventions to screen for, identify, and develop drugs, in exchange for a small upfront fee, minimal annual license maintenance fees, and deferred payment for the use of the Mount Sinai patents during their life, in the form of a one percent royalty on the sales of all to-be developed and commercialized "Licensed Products," i.e., any drugs identified and developed using Mount Sinai's drug-discovery tools. The License Agreement required Neurocrine to provide Mount Sinai with annual reports and annual listings of Licensed Products—i.e., drug candidates—identified and discovered using Mount Sinai's technology that modulate the activity of the GnRH-R.

6. Most important for purposes of this action, the License Agreement provided that Neurocrine must obtain Mount Sinai's prior written consent before sublicensing to any non-affiliated company the licensed rights to identify, screen for, and develop the defined "Licensed Product" drug candidates. The ability of a licensee to sublicense to others is a valuable right. The Parties, through the language agreed upon in 1999, intentionally deferred negotiation of that right until such time as Neurocrine would want or need to grant a sublicense to a non-affiliated drug development partner.

Significance of Sublicensing Provisions in Pharmaceutical Development

7. In the pharmaceutical industry, sublicensing of product development rights plays an extremely important role to bridge the gap from the initial drug discovery stage, to the final stages of product development, commercial manufacture, and marketing of an approved drug. Many biopharmaceutical companies are small, with limited financing, and are devoted principally, or solely, to basic research functions. They often lack the size, regulatory and marketing expertise, distribution infrastructure, and other resources to conduct, manage, and fund expensive Phase III clinical trials; to take a drug through the U.S. Food and Drug Administration ("FDA") drug approval process; and to manufacture, market, and distribute the drug after approval. It is common for smaller research-focused companies, after identifying a drug candidate that shows early promise in pre-clinical studies for the treatment of a particular disease or disorder, to raise capital to cover the expense of small scale (Phase I and Phase II) trials on human subjects, and then to sublicense the development and commercialization rights to a larger drug company if the initial trials are successful. Sublicensing such rights is an important and typically profitable event in the life of drug development efforts, particularly for small biopharmaceutical companies that focus primarily on early stage research and the identification of drug candidates.

8. Once a drug candidate's promise has been established through early-stage clinical trials, future sales and profits may be predicted based on market size and potential market penetration. The buyer of drug development rights will often pay a very large up-front fee for the right to take over the drug development and commercialization program (up to $100 million or more depending on the licensed drug's potential), with future contingent milestone payments, frequently hundreds of millions of dollars or more, being made as the drug successfully proceeds

through subsequent clinical trials, obtains FDA marketing approval, and is commercialized.

9. The licensors of the original, underlying foundational intellectual property, such as non-profit academic and research institutions like Mount Sinai, typically receive a substantial portion, usually 25-35%, of the sub-licensing income paid by the pharmaceutical company that takes over the development program or process.

Neurocrine's Use of Mount Sinai's GnRH Technology

10. Neurocrine used the foundational drug-discovery technology it licensed from Mount Sinai to screen for, identify, and begin development of GnRH-R antagonist drugs for the treatment of endocrine diseases and disorders. Neurocrine relied on and used Mount Sinai's patented technology as the foundation for its drug discovery and development program, and used the licensed Mount Sinai technology to discover and begin developing at least one commercially viable drug, "Elagolix," which has shown promise in the treatment of two serious conditions, endometriosis and uterine fibroids.

11. Endometriosis affects an estimated 170 million women worldwide, and is a condition in which uterine lining tissue grows outside the uterus, typically resulting in chronic pain, infertility, and abnormally heavy and prolonged menstrual periods. Uterine fibroids are non-cancerous growths found inside, outside, or in the wall of the uterus, which can cause pelvic pain, reproductive complications, and severe bleeding possibly leading to anemia. It is estimated that as many as 75% of women will develop uterine fibroids at some point during their lives.

12. During the course of its drug development program, Neurocrine relied on Mount Sinai's drug-discovery tools to screen for, identify, and begin development of potential drug candidates that modulate the activity of the GnRH-R. Yet Neurocrine, in violation of the terms of the License Agreement, failed to provide annual reports, and failed to identify on an annual

basis what drugs had been identified or discovered by it using the licensed Mount Sinai drug-discovery tools.

Neurocrine's Breach of the 1999 License Agreement

13. Despite the License Agreement's clear prohibition against granting any sublicenses without Mount Sinai's prior written consent, on June 15, 2010, Neurocrine entered an agreement with Abbott International Luxembourg S.à.r.l. ("Abbott"), now AbbVie Inc., (hereafter, "AbbVie"), under which Neurocrine transferred to AbbVie its entire GnRH antagonist drug program, and transferred and sublicensed to AbbVie all rights to research, develop, and commercialize Elagolix and other GnRH antagonist drugs that had been, and would in the future be identified using Mount Sinai's foundational drug-discovery tools ("Neurocrine-AbbVie Agreement").

14. The Neurocrine-AbbVie Agreement provided for a transfer of all of Neurocrine's drug research and development technology related to the transferred GnRH antagonist drug program to AbbVie; provided that neither AbbVie nor Neurocrine would engage in any competitive drug development; and further gave AbbVie the power to control and direct the continued use—whether by AbbVie or by Neurocrine—of the Mount Sinai drug-discovery tools covered by the License Agreement to research and develop both Elagolix and follow-on GnRH antagonist drugs for women's and men's health.

15. In exchange for the transfer of its entire GnRH antagonist program to AbbVie, Neurocrine received:

- $75 million in up-front payments;
- Up to $530 million in future drug development milestone payments as Elagolix and certain "follow-on" drug compounds proceed through FDA approval and

commercialization; and

- Substantial royalties (significantly greater than the 1% due to Mount Sinai under the License Agreement) on AbbVie's future sales of Elagolix and "follow-on" drug products.

16. Neurocrine entered into the Neurocrine-AbbVie Agreement and transferred these rights to AbbVie without first seeking or obtaining Mount Sinai's written consent to grant a sublicense, in breach of the clear requirements of the License Agreement. The Neurocrine-AbbVie Agreement constitutes an unpermitted (i.e., unconsented) sublicense in at least three ways:

- First, Neurocrine sublicensed to AbbVie what Mount Sinai had licensed to it, namely all rights to research and develop Elagolix and other currently unknown follow-on compounds that are "Licensed Products."
- Second, AbbVie obtained Neurocrine's promise to transfer to AbbVie all technology and assets related to those compounds and products.
- Third, the Neurocrine-AbbVie agreement—and its express terms—transferred to AbbVie the right and power to control and direct research and development into both Elagolix and as-yet unidentified "follow-on" compounds, or "next-generation" GnRH antagonists, including use of Mount Sinai's patented drug-discovery tools to do so.

17. Neurocrine's breach of the License Agreement deprived Mount Sinai of the full value of the foundational intellectual property it had licensed to Neurocrine in 1999, took from Mount Sinai the value of the right to sublicense that had been retained in the License Agreement, and deprived Mount Sinai of the expected—and bargained for—opportunity to negotiate a

reasonable and fair share of the sublicensing revenues, including but not limited to up-front and milestone payments, and any other payments that Neurocrine has received, and will in the future receive, from AbbVie.

18. Neurocrine, by its breach of its obligation to seek and obtain Mount Sinai's consent, also prevented Mount Sinai from protecting other interests, such as rights to royalty payments, audit rights, and other matters in the transaction that resulted in the Neurocrine-AbbVie Agreement. Based on public records, Neurocrine has received to date at least $105 million in sublicensing income and will receive hundreds of millions of dollars more. As discussed, Mount Sinai is entitled to a substantial percentage of sublicensing income and will suffer hundreds of millions of dollars in damages as a result of Neurocrine's breach.

19. Neurocrine breached, and continues to breach, its obligations under the License Agreement, as alleged more fully below, and Mount Sinai seeks relief from the Court, including: (a) a judgment in Mount Sinai's favor and against Neurocrine for breach of contract in an amount to be determined at trial; (b) a declaration entitling Mount Sinai to a share of future payments Neurocrine receives; (c) costs; and (d) such other and further relief as the Court may deem just and proper.

THE PARTIES AND RELEVANT NON-PARTIES

20. Plaintiff, formerly known as Mount Sinai School of Medicine of the City University of New York, is a New York education corporation, organized under the New York Education Law and chartered by the Board of Regents of the State of New York. Its sole member is Mount Sinai Health System, Inc., a not-for-profit corporation organized under the laws of the State of New York. Mount Sinai has a principal place of business at 1 Gustave L. Levy Place, New York, NY 10029-6574. Mount Sinai owns and controls certain rights in technology for the identification, discovery, and screening of drug compounds that interact in the

human body with receptors for the hormone known as GnRH. Mount Sinai's drug-discovery tools are foundational in the identification, screening, and development of drugs for the treatment of a number of endocrine disorders, and Mount Sinai has the exclusive right to grant licenses to the patented technology directed thereto.

21. Neurocrine is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 12780 El Camino Real, San Diego, CA 92130. Neurocrine is in the business of, among other things, developing pharmaceuticals for use in neurological and endocrine diseases and disorders.

22. On information and belief, non-party AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. On information and belief, AbbVie is in the business of, among other things, pharmaceutical development, manufacturing and sales.

JURISDICTION AND VENUE

23. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because there is complete diversity of citizenship between the Parties, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

24. As alleged more fully herein, the Court has personal jurisdiction over Neurocrine because, among other things: (a) by entering into the License Agreement to obtain the rights to use Mount Sinai's intellectual property to screen for, identify, and develop drugs, Neurocrine purposefully engaged in an on-going contractual relationship with Mount Sinai, a New York corporation; (b) Neurocrine expressly consented to a New York choice-of-law clause in the License Agreement; (c) the License Agreement requires Neurocrine to perform the contract in New York, i.e., send reports and payments to Mount Sinai in New York State; and (d) under the

terms of the License Agreement, Neurocrine is subject to Mount Sinai's supervision in New York State.

25. Venue is proper in this judicial district in accordance with 28 U.S.C. § 1391 because Neurocrine is subject to personal jurisdiction in the District and thus resides here for venue purposes, and because a substantial part of the events and omissions giving rise to this action occurred in the District.

FACTUAL BACKGROUND

A. Mount Sinai Successfully Licenses Its Foundational, Patented Technology in Exchange for the Rights to Sublicensing Income and Royalty Payments

1. Mount Sinai's World-Leading Medical Research Includes Development of Foundational Technologies that Result in Marketed Products of Great Public Benefit

26. Mount Sinai is world renowned for its groundbreaking medical and scientific inquiry, discovery, and development, and is the home to a full spectrum of research laboratories, institutes, and centers across scientific disciplines. Mount Sinai's leading research includes improvements in cancer treatments, depression, genetic engineering, and biotechnology. Mount Sinai is the home of researchers across thirty-four academic departments and twenty-two multidisciplinary institutes, including the Friedman Brain Institute, and the Ronald M. Loeb Center for Alzheimer's Disease. In 2014 alone, Mount Sinai received $247.1 million in National Institutes of Health ("NIH") funding for its foundational research.

27. Mount Sinai's medical and biopharmaceutical research programs investigate, discover, and develop treatments and technologies in critically important and frontline areas. Recent discoveries include identification of the first common gene variant linked to autism; performing the first successful surgical composite tracheal transplant; performing the first U.S. implantation of a new device for aortic stenosis (narrowing of aortic valve in the heart); and

identifying a gene in the brain–*OLIG2*–that may play a causal role in the development of schizophrenia.

28. Through its licensing initiatives, Mount Sinai's foundational research has resulted in seventeen marketed products and technologies, including the FluMist vaccine; Fabrazyme®, a treatment for Fabry disease; and the Annuloplasty Ring, a device for repairing heart valves. Many other licensed products are currently in development. Mount Sinai also works with industry to develop research partnerships and to ensure that Mount Sinai's discoveries lead to real-world applications that benefit the public.

29. Mount Sinai's GnRH-R technology is an example of Mount Sinai's foundational research. As a drug-discovery tool, Mount Sinai's GnRH-R technology allows for the identification, discovery, and development of new drugs for the treatment of diseases affected by the GnRH chemical signaling pathway, such as reproductive and endocrine disorders, including endometriosis and uterine fibroids, discussed above.

2. Mount Sinai Routinely Licenses the Rights to Use, Develop, and Sublicense its Foundational Technology in Exchange for a Portion of Royalty Payments and Sublicensing Income

30. When universities and other research institutions such as Mount Sinai license out their foundational technology, the financial considerations received from the licensee fall into one or more of several categories, including but not limited to: up-front fees, license maintenance fees or minimum annual royalties, royalties based on sales of the commercialized product, and a percentage of sublicensing income received by the licensee from any of its sublicensees.

31. The ability of a licensee, including those who license technology from research institutions such as Mount Sinai, to sublicense to others is an important and valuable right. Licensees of foundational biopharmaceutical technology such as drug-discovery tools are often small and modestly funded research companies. It is understood by the out-licensing research

institutions and by the licensees that the licensee will perform the initial research into potential drug candidates, and will almost certainly need to partner later on with a major pharmaceutical company in order to successfully complete product development and bring a commercial drug and follow-on products to market. As noted above, it is often critical for these smaller biotechnology companies to sublicense the development and commercialization rights they have received to foundational research tools to large drug companies that have the regulatory and marketing expertise, distribution infrastructure, and other resources to conduct, manage, and fund expensive Phase III clinical trials; to take a drug through the FDA approval process; and to manufacture, market, and distribute the drug after approval. In exchange for the sublicense granting the right to use the original licensor's discovery tool, the original licensee receives substantial payments, or sublicensing income, from the large drug company sublicensee. These payments may take numerous forms, including but not limited to up-front fees, royalties based on sales by the sublicensee, development milestone payments, and sales milestone payments.

32. Receipt by the research institution licensor of a percentage of any sublicensing income received by the licensee is a critical term in foundational licenses, particularly where the licensee is likely to enter into collaborations or partnerships with third parties in the future. It is typical for licensors of intellectual property, including research institutions such as Mount Sinai, to negotiate for and receive a share of both royalties and sublicensing income paid to the licensee by the sublicensee drug development companies that subsequently take over the drug development rights.

33. Sublicensing income generally includes any payments received by the licensee from an authorized sublicensee. In particular, income received by the licensee that qualifies as sublicense income may include a portion of the royalty payments received by the licensee from

the sublicensee for sales of the licensed product, upfront or milestone payments received by the licensee, or any other payments made by the sublicensee to the licensee. Often, but not always, the negotiation for a licensor's fair share of sublicensing and other revenues to be received from sublicensees occurs when the initial license is negotiated. The university licensor and the licensee may also require consent by the university before sublicenses may be granted.

34. Often the original licensee will agree to compensate the licensor, i.e., a university or other research institution, by paying not only a royalty on all future sales of the licensed drug or device that derives from the licensee's use of the licensor's patents or other licensed intellectual property, but also by paying a substantial percentage of other compensation the licensee receives from any sublicensee. Typically the sublicensee is a major pharmaceutical company that acquires the rights to take over the licensee's licensed research, product development efforts, and identification and development of related follow-on drugs or drug products, in the event that a successful product is discovered. In their role of licensor, research institutions routinely obtain the right to receive at least 25-35% of all non-royalty sublicensing income paid by any future sublicensee, and may also share in any increased royalties, as a condition of agreeing to allow the rights to be sublicensed.

35. Similar to typical university and research institution licensing practices, since the 1990s and through today, it has been and remains Mount Sinai's policy and practice to require licensees of its foundational intellectual property to agree to pay, in addition to an up-front license fee and annual renewal fees, a reasonable royalty on the future sales of licensed products, and also a share of any other revenue received from any future sublicensees.

36. Mount Sinai has been very successful in conducting cutting edge research, and also very successful in licensing its important biopharmaceutical and other medical inventions.

In 2014 alone, Mount Sinai received approximately $47 million in licensing proceeds for its technology and filed 155 new patents. As noted above, these licensing efforts have resulted in a significant number of products reaching market, directly benefiting healthcare consumers, and the proceeds have allowed Mount Sinai to continue, and expand, its important medical research in the public interest.

B. Mount Sinai's Dr. Sealfon Invented Platform Technology Allowing the Discovery and Development of Drugs for Treatment of Endocrine Disorders

1. Dr. Sealfon Identifies the GnRH Receptor DNA Sequence and Clones the GnRH Receptor

37. Dr. Sealfon is a board certified Neurologist and an internationally renowned researcher in the areas of cellular and chemical reactions in the brain, and systems biology. After receiving his M.D. in 1982 from Columbia University College of Physicians & Surgeons in New York, NY, Dr. Sealfon performed his Internship in Internal Medicine and received his Residency training in Neurology at Massachusetts General Hospital in Boston, MA. Thereafter, Dr. Sealfon completed his Fellowship in Neuroscience at Mount Sinai, and in 1988 he joined the faculty at Mount Sinai as an Assistant Professor.

38. Dr. Sealfon focused his earliest research at Mount Sinai on the endocrine system, the system of glands that produce and secrete hormones into the circulatory system that are then carried to targets and organs within the body. In particular, Dr. Sealfon concentrated his research on GnRH, a hormone synthesized and released from within the hypothalamus. After release from the hypothalamus, GnRH is carried through the circulatory system to the pituitary gland where it binds to and activates the GnRH-R located primarily in the pituitary, among other places. GnRH binding to GnRH-R leads to a complex cascade of events starting with the synthesis and secretion of gonadotropins—follicle-stimulating hormone, and luteinizing hormone—that act on the gonads (i.e., testes and ovary), and ultimately play pivotal roles in,

among other things, sperm maturation in men and ovulation in women. GnRH and GnRH imbalance are implicated in disorders including prostate cancer, ovarian cancer, breast cancer, endometriosis, uterine fibroids, prostatic hyperplasia, and precocious puberty. Control of GnRH action through the use of GnRH agonists, which bind to the GnRH-R to promote a biological response, and GnRH antagonists, which bind to the GnRH-R to inhibit or dampen a biological response, had been considered a promising approach for these and other endocrine disorders.

39. In the 1990s, when Dr. Sealfon began his research in the GnRH field, no one had previously been able to clone the GnRH-R, or develop stable cell lines expressing the GnRH-R. Yet researchers understood at the time that identifying the DNA sequence of the GnRH-R, cloning the GnRH-R gene, and making such cell lines would advance the evaluation of the complex hormonal signaling system regulating the release of GnRH and gonadotropin production.

2. Dr. Sealfon Invents, and Mount Sinai Patents, the Foundational Tools for the Discovery of Drugs that Modulate GnRH-R Activity

40. Dr. Sealfon ultimately identified the GnRH-R DNA and cDNA sequences, successfully cloned the GnRH-R, made stable cell lines that expressed the GnRH-R, and invented a method for using the invented cell lines to identify drug compounds that modulate GnRH-R molecular signaling. Dr. Sealfon's inventions resulted in drug-discovery tools and technology that allow for the screening, identification, and development of compounds that stimulate or inhibit GnRH-R activity, and therefore could be candidates for the treatment of endocrine disorders and diseases.

41. Dr. Sealfon's inventions covering these foundational drug-discovery tools resulted in a number of domestic and foreign patents, including U.S. Patent Nos. 5,750,366 ("the '366 patent"), and 5,985,583 ("the '583 patent").

42. The ’366 patent, entitled “Cloning and Expression of Gonadotropin-Releasing Hormone Receptor,” was duly and legally issued by the U.S. Patent and Trademark Office (“PTO”) on May 12, 1998. Mount Sinai is the owner of all right, title, and interest in and to the ’366 patent by assignment.

43. The ’583 patent, entitled “Cloning and Expression of Gonadotropin Releasing Hormone Receptor,” was duly and legally issued by the PTO on November 16, 1999. Mount Sinai is the owner of all right, title, and interest in and to the ’583 patent by assignment.

C. Neurocrine Forms To Research and Develop Drugs To Treat Neurologic and Endocrine Disorders

44. Neurocrine was founded in 1992. Neurocrine is a small biopharmaceutical research and development company established to focus its research on identifying and developing drugs for treatment of neurologic and endocrine disorders. In particular, Neurocrine desired to identify and commercialize one or more orally deliverable (i.e., small molecule) drug compounds for use in treating a number of endocrine disorders.

45. Neurocrine in particular desired to identify and develop small molecule GnRH antagonist drugs that could be taken by patients orally for the treatment of endocrine disorders such as endometriosis. Neurocrine became aware of Dr. Sealfon’s cutting edge research and inventions and realized the importance of Mount Sinai’s patented drug-discovery tools to achieving its goal of identifying and developing such a drug.

46. In or about early 1999, Neurocrine engaged with Mount Sinai to obtain a license to use the patent-protected drug-discovery tools invented by Dr. Sealfon and covered by, among other patents, the ’366 patent and the ’583 patent. During the license negotiations, Mount Sinai understood that Neurocrine desired to use the patent-protected technology that Dr. Sealfon had invented to identify and screen for, and then develop for commercial sale, synthetic organic drug

candidate molecules that would be beneficial in treating one or more endocrine disorders.

47. The Parties understood that the process of screening for and identifying drug candidate molecules, conducting further laboratory research, and engaging in development activities such as clinical trials to obtain marketing approval from FDA would take many years. As such, the Parties understood that drug products discovered using Mount Sinai's patent-protected technology likely would not be approved by FDA and sold on the market until near, or after, the expiration of the patents covering such technology. Further, Neurocrine was at that time (and remains today) a small research company without the size, resources, or marketing capabilities to fully develop and commercialize the drugs that Neurocrine expected to identify and develop based on its use of the Mount Sinai drug-discovery tools it desired to use.

D. Mount Sinai Licenses Dr. Sealfon's Technology to Neurocrine

1. The Parties' Contract Licensed Neurocrine To Identify, Screen for, and Develop Drug Products Resulting from Use of Mount Sinai's Patented Drug-Discovery Tools

48. Following negotiations, Mount Sinai and Neurocrine entered into the License Agreement with an effective date of August 27, 1999. (*See* Exhibit 1.) The license is broad, granting Neurocrine a "worldwide license to make and use the subject matter covered under the Licensed Patent Rights to identify, screen for, and/or develop products." (*Id.* § 1.6.)

49. Neurocrine has explained repeatedly over the years in its filings with the Federal Securities and Exchange Commission ("SEC"), for example in its Form 10-K annual report filing for its fiscal year ended December 31, 2014, that the License Agreement is a "license to certain patents and patent applications related to GnRH, to develop and commercialize licensed products worldwide." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 9, 2015).

2. Recognizing the Foundational Nature of Mount Sinai's Patented Technology, Potential Drugs Resulting from Neurocrine's Use of the Patents Were Termed "Licensed Products" and Neurocrine Agreed To Pay Mount Sinai Royalties on All Future Sales of Licensed Products

50. Due to the foundational nature of Mount Sinai's patented drug discovery tools, the Parties recognized and agreed that any drugs to be identified using the Mount Sinai discovery tools would be defined as "Licensed Products." Defining "Licensed Products" in this way serves to recognize that both the identification of potentially beneficial compounds, and the subsequent development of those identified drug candidates through clinical trials and the FDA approval process, would depend on the use of Mount Sinai's licensed inventions. Accordingly, products to be identified and developed by Neurocrine were defined by the Parties in Section 1.5 of the agreement: "'Licensed Products' means any product that modulates the activity of the GnRH-R and is (a) identified or discovered using" the GnRH-R claimed by Mount Sinai's patents and applications, "or (b) could not have been discovered or developed without infringing the Licensed Patent Rights." (Ex. 1 § 1.5.)

51. Neurocrine agreed to pay Mount Sinai royalties on all sales made of "Licensed Products." Because Neurocrine was expected to obtain income from sales of the fully developed Licensed Product(s) several years in the future, the Parties agreed that Neurocrine, in consideration for its right to use the patented tools during the more than 16 years of patent life since it licensed the patents from Mount Sinai, would be obligated to pay Mount Sinai a royalty of one percent (1%) of net sales of Licensed Products until the later of fifteen years after the date of first commercial sale of the first Licensed Product, or the expiration of the last to expire of the licensed patents. (*Id.* § 3.3.) The License Agreement also provides Mount Sinai the right to audit sales of Licensed Products so as to be assured that royalty payments are being made consistent with all provisions of the License Agreement. (*Id.* § 3.7.)

52. Neurocrine has recognized in its SEC filings that it is "obligated to pay Mount Sinai a royalty equal to 1% of net sales of licensed products." *E.g.*, Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 9, 2015).

3. Neurocrine Assumed Annual Development Reporting Obligations

53. Because of Neurocrine's small size and limited resources, and the length of time expected to take to develop the resulting drugs and bring them to market, the Parties agreed that Neurocrine would pay a nominal up-front license fee of $50,000 and annual license maintenance fees of $10,000. (Ex. 1 at §§ 3.1, 3.2.) In addition, Neurocrine agreed to provide annual "Development Reports." These were to be provided "[o]n or before January 1 of each year," and were to include: "(i) a complete written list of Licensed Products discovered in the previous year using Licensed Patent Rights, and, (ii) . . . a report describing the development status in the previous year of each Licensed Product(s), in particular the drug development milestones that were achieved." (*Id.* § 3.5.)

4. The License Agreement Prohibits Neurocrine from Sublicensing its Rights Under the License to Any Person Without First Obtaining Mount Sinai's Advance Written Consent

a. During Negotiations of the License Agreement, Neurocrine Sought, but was Refused, an Unconditional Right To Sublicense

54. During the 1999 negotiation, the Parties recognized that Neurocrine, because of its small size and limited resources, probably would not have the resources, funding, regulatory expertise, or manufacturing, marketing or distribution capabilities needed to complete the research and development of the anticipated Licensed Products, and that Neurocrine would therefore eventually need to sublicense out the further research, development, marketing, and commercialization activities to a major drug company. As alleged above, sublicensing of such rights is an important and typically profitable event in the life of drug development efforts.

55. During the negotiations with Mount Sinai, Neurocrine sought to obtain the unfettered right to sublicense out the rights it was licensed to a major pharmaceutical company, without sharing in any of the typical sublicense income. Mount Sinai did not agree to this proposal, and did not agree to provide Neurocrine an unconditional right to sublicense drug development rights in the future.

b. As Reflected in Section 2.1(c) of the License Agreement, the Parties Envisioned Later Negotiation over Any Future Sublicense and that Mount Sinai Would, Consistent with Industry Practice, Secure Additional Consideration for Consenting to Any Such Sublicense

56. The License Agreement provides for a later negotiation to occur between Neurocrine and Mount Sinai should Neurocrine determine that it wanted to sublicense any non-affiliated entities in the future. That is, the Parties agreed that Neurocrine may only grant sublicenses after negotiating with Mount Sinai and obtaining its prior written consent. Thus, Section 2.1(c) of the License Agreement provides, as relevant: "Licensee shall have the right to grant sublicenses under the License only with the prior written consent of Licensor," i.e., Mount Sinai. Section 2.1(c) allows sublicensing without Mount Sinai's prior written consent only "in any country to at most one of [Neurocrine's] Affiliates in such country on prior notice to Licensor." The section concludes by requiring that any sublicense allowed "shall be subject and subordinate to the terms and conditions of this Agreement." (*Id.* § 2.1(c).)

57. The purpose of this prior-written-consent provision was to ensure that the value of any future sublicense, and appropriate sharing of compensation to be paid by the sublicensee for the drug development and research rights obtained, could be evaluated and negotiated at the same time that the sublicensing deal was being negotiated. The Parties expected, and the License Agreement requires, a negotiation to take place setting appropriate compensation to Mount Sinai, as well as assuring that any sublicense would contain terms and conditions

protecting Mount Sinai's interests, e.g., assurances that it will receive development reports from the sublicensee taking over the development efforts, that both Neurocrine and any permitted sublicensee will be jointly and severally responsible for making royalty payments due on sales of Licensed Products under terms acceptable to Mount Sinai, and that Mount Sinai will have appropriate sales audit and other rights.

E. Neurocrine Uses the Licensed Technology To Discover Elagolix for Treatment of Endocrine Disorders

58. Neurocrine subsequently used the patent-protected drug-discovery tools it licensed from Mount Sinai to establish its GnRH antagonist program, and used the licensed tools to screen for and identify at least one drug, which it named "Elagolix," as a strong candidate for treating a number of endocrine disorders. Neurocrine describes Elagolix as an orally administered formulation of GnRH antagonist, believed to alter the level of pituitary GnRH suppression and, as a result, titrating circulating estrogen levels. Neurocrine states that it believes that Elagolix will provide relief from the pain associated with conditions such as endometriosis and uterine fibroids, without a need to actively manage bone loss. Mount Sinai's licensed tools were essential both to Neurocrine's GnRH antagonist program and to Neurocrine's (and later, AbbVie's) identification and development of Elagolix and other "follow-on" compounds.

59. Neurocrine did not timely provide progress reports to Mount Sinai—for those years in which Neurocrine provided a report at all—nor did it provide Mount Sinai annually with a "complete written list of Licensed Products discovered in the previous year" using the licensed Mount Sinai discovery tools, as it was obligated under Section 3.5 of the License Agreement.

60. Neurocrine did, however, use the discovery technology it licensed from Mount Sinai to identify Elagolix as a potential drug candidate. Neurocrine announced in late 2001 that

it had "selected an orally active GnRH antagonist development candidate for the treatment of endometriosis, uterine fibroids and prostate cancer" and was "set to begin Phase 1 clinical studies in the fourth quarter of 2001." Press Release, Dow Jones News Service, Neurocrine Biosciences 3Q Net 9c/Shr (Nov. 1, 2001). Neurocrine announced in January 2006 that it was testing Elagolix for possible treatment of endocrine disorders, including endometriosis. *See, e.g.*, Press Release, Neurocrine, Neurocrine Biosciences Reports Fourth Quarter and Year-End 2005 Results (Jan. 23, 2006).

F. Neurocrine Publicly Announces Positive Results in Elagolix Phase I and Phase II Clinical Trials

61. In addition to beginning studies on the use of Elagolix for the treatment of endometriosis and uterine fibroids, Neurocrine also filed an Investigational New Drug ("IND") application with FDA in the fourth quarter of 2005 to initiate Phase I studies in males for the treatment of benign prostatic hyperplasia.

62. In September 2006, Neurocrine announced positive results from a six-month, Phase II study of patients with endometriosis. The results of this study were reported as showing that Elagolix was safe, well tolerated, and provided a reduction in pain in endometriosis patients. Press Release, Neurocrine, Neurocrine Biosciences, Inc. (NBIX) Announces Results From Follow-Up Phase II Study With Its Orally Active GnRH Receptor Antagonist In Endometriosis (Sept. 12, 2006).

63. In September 2008, Neurocrine publicly announced that the "Elagolix PETAL Study in Endometriosis" met primary bone mineral density and secondary efficacy endpoints, and Neurocrine further announced that these results showed that the drug did not induce significant bone loss, and provided "rapid and significant pain reduction in endometriosis symptoms." Press Release, Neurocrine, Neurocrine Biosciences Announces Successful Elagolix

PETAL Study in Endometriosis (Sept. 2, 2008).

64. In March 2009, Neurocrine announced further positive results from the "Lilac PETAL Study," the fourth Phase II clinical trial of Elagolix, and Neurocrine further announced that these results showed that Elagolix provided clinical improvement of symptoms and an excellent safety and tolerability profile. Press Release, Neurocrine, Neurocrine Announces Top-Line Results From 702 Study (Lilac PETAL Study) of Elagolix for Treatment of Endometriosis Pain (Mar. 25, 2009).

G. Neurocrine Informs Mount Sinai that Neurocrine Is in Discussions To Enter into a Sublicense, but Never Obtains Mount Sinai's Consent to Any Sublicense

65. Although Neurocrine consistently failed to send Mount Sinai the annual development reports and annual listings of the "Licensed Product" drugs it had identified or discovered using Mount Sinai's drug discovery tools, as required by Section 3.5 of the License Agreement, a Neurocrine representative did call Mount Sinai in 2008 and advised that the Elagolix drug, then in clinical Phase II trials for treatment of endometriosis, was a Licensed Product under the License Agreement. The Neurocrine representative stated that Neurocrine would be paying Mount Sinai a royalty on future sales of the drug once FDA approval was obtained.

66. The Neurocrine representative made the statements above concerning the development of Elagolix in the context of also advising Mount Sinai that Neurocrine was in discussions to sublicense the licensed drug development program to an undisclosed third party, and that any products resulting from that effort would be covered by the License Agreement. During the call, the Neurocrine representative recognized that Neurocrine would need to negotiate an amendment to the License Agreement, or otherwise obtain Mount Sinai's consent, to allow the planned sublicensing to proceed.

67. Neurocrine did not follow-up with Mount Sinai to obtain consent to its planned sublicense, and Neurocrine did not timely provide the annual development report for each of the nine years between 2003 and 2011 inclusive, in further violation of the License Agreement. Neurocrine did, however, continue testing Elagolix in clinical trials and publicly reporting successful results. For example, in December 2009 Neurocrine issued a press release announcing positive "topline" results from its fifth Phase II study of Elagolix, a clinical trial it referred to as the "Tulip PETAL" study. Press Release, Neurocrine, Neurocrine Announces Top-Line Results From 703 Study (Tulip PETAL Study) of Elagolix for Treatment of Endometriosis Pain (Dec. 9, 2009). And on May 24, 2010, Neurocrine announced positive results of a subsequent "Daisy PETAL" Phase II study. Press Release, Neurocrine, Neurocrine Biosciences Announces Positive Results in Daisy PETAL Study (May 24, 2010).

68. During the period September 30, 2009 through the end of May 2010, Neurocrine's prospects and market value rose significantly, primarily because of the promising Elagolix clinical trial results, including the May 24, 2010 announcement of positive "Daisy PETAL" Phase II study results.

69. Neurocrine has stated that its Phase I and Phase II data for Elagolix in women support the drug's potential use in other women's health indications, such as menorrhagia (excessive uterine bleeding) and primary dysmenorrhea, which commonly result from underlying endometriosis, uterine fibroids, or adenomyosis and, as such, may be amenable to treatment with a nonpeptide GnRH antagonist. Additionally, Neurocrine has stated that premenstrual dysphoric disease, polycystic ovarian syndrome, breast cancer prevention, precocious puberty, or even contraception may also be appropriate indications for an oral nonpeptide GnRH antagonist.

H. On June 15, 2010, Neurocrine and Abbott, One of the Largest Drug Companies in the World, Enter into an Agreement Licensing the Research, Development, and Commercialization of Elagolix and Other GnRH Antagonist Drug Products to Abbott

1. Neurocrine Transfers its Entire GnRH Antagonist Program, Including the Development of Elagolix, to Abbott Without Mount Sinai's Consent

70. Neurocrine recognized in its Form 10-K annual report filed with the SEC in February 2009 that "in-licensed technologies, such as the GnRH receptor we license from Mount Sinai School of Medicine will be important for future collaborations for our elagolix program." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 3, 2009). And in its Form 10-K report filed February 2010 with the SEC, Neurocrine explained that the license from Mount Sinai was among those so important that, "[i]f we were to default on our obligations . . . we could lose some or all of our rights to develop, market and sell products covered by the licenses." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 5, 2010). As noted in paragraph 49, above, Neurocrine has, in its SEC filings, described the License Agreement as one "to develop and commercialize licensed products worldwide." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 9, 2015).

71. Without seeking or obtaining Mount Sinai's consent as required under the License Agreement (*see supra*, paragraphs 54 through 57), Neurocrine and pharmaceutical giant Abbott jointly announced, on June 15, 2010, that they had entered into a "collaboration agreement to develop and commercialize Elagolix for the treatment of endometriosis-related pain." Press Release, Neurocrine, Abbott and Neurocrine Announce Global Agreement to Develop and Commercialize Elagolix for the Treatment of Endometriosis (June 16, 2010) (a copy of the Press Release is attached to the Complaint as Exhibit 2.) The Neurocrine-Abbott press release further explained that under their agreement "Abbott will receive worldwide exclusive rights [from Neurocrine] to develop and commercialize elagolix and all next-generation GnRH antagonists,

for women's and men's health." *Id.* The companies also reported that Elagolix "will be evaluated for the treatment of uterine fibroids," and that the agreement also provided Abbott with "the potential for additional compounds in earlier stage development." *Id.*

72. In or about 2013, AbbVie was spun out of Abbott, and AbbVie took with it the pharmaceutical development and marketing and commercialization programs previously run by Abbott, including the development of Elagolix and the "follow-on" compounds that are the subject of the Neurocrine-Abbott agreement. The planned spin out of AbbVie was announced in October 2011, and closed in or about January 2013. Press Release, Abbott, Abbott to Separate into Two Leading Companies in Diversified Medical Products and Research-Based Pharmaceuticals (Oct. 19, 2011); Press Release, Abbott, Abbott Completes Separation of Research-Based Pharmaceuticals Business (Jan. 2, 2013). On information and belief, the Neurocrine-Abbott agreement was transferred and assigned to AbbVie, and AbbVie has since been responsible for performing that agreement. That agreement is hereafter referred to as the "Neurocrine-AbbVie Agreement." (A censored (redacted) version of the Neurocrine-AbbVie Agreement, which is all that Mount Sinai has been permitted to obtain, is attached to the Complaint as Exhibit 3).

73. The joint Neurocrine-Abbott press release and subsequent Neurocrine filings with the SEC explain that, as is typical of such drug development agreements, AbbVie made an initial up-front payment of $75 million to Neurocrine, and agreed to pay Neurocrine up to an additional $530 million contingent upon the achievement of certain "development, regulatory and commercial milestone[s]." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 9, 2015); *see also* Ex. 2, Press Release, Abbott, Abbott and Neurocrine Announce Global Agreement to Develop and Commercialize Elagolix for the Treatment of Endometriosis (June

16, 2010).

74. As alleged below in paragraphs 76-78, Neurocrine refused to provide Mount Sinai a complete, uncensored copy of Neurocrine-AbbVie Agreement. Even without access to the Neurocrine-AbbVie Agreement, it is clear from the joint press release and other documents that through its agreement with Abbott/AbbVie, Neurocrine effected an unauthorized, unconsented-to sublicense of the license granted to Neurocrine by Mount Sinai. The Neurocrine-AbbVie Agreement:

- Transfers to AbbVie what Mount Sinai had licensed Neurocrine to do, namely, an exclusive worldwide license "to research, develop, make," and commercialize, Elagolix and other GnRH receptor antagonist products, including "next-generation," and "follow-on" compounds, identified and developed using the Mount Sinai licensed drug discovery tools, (Ex. 3 § 3.1; *see also* Ex. 2 Press Release, Neurocrine, Abbott and Neurocrine Announce Global Agreement to Develop and Commercialize Elagolix for the Treatment of Endometriosis (June 16, 2010));
- Sets out the terms and conditions on which Neurocrine and AbbVie are to collaborate in connection with the research, development, and commercialization of GnRH receptor antagonist products identified and developed using the Mount Sinai drug discovery tools, (Ex. 3 at 1);
- Calls for a collaboration in connection with the research, development and commercialization of Elagolix and other unidentified "Follow-on" compounds, still to be identified and further developed, (*id.* (the definition of "Follow-on" compounds is redacted in the Neurocrine Abbot Agreement));

- Commits AbbVie and Neurocrine to an "Exclusive Collaborative Effort," i.e., they mutually agreed that neither would compete with respect to, or develop any other, similar drugs, (*id.* § 2.3);
- Calls for Neurocrine to transfer to AbbVie all the technology and assets related to all the drug compounds and products, including the as-yet unidentified "follow-on" GnRH receptor antagonist drugs (*id.* § 6.1(d)); and
- Provides AbbVie with the right and power to take over, and direct and control, from the date the agreement was entered in June 2010, the contemplated drug research and development, including using, or directing Neurocrine to use as AbbVie desired, the Mount Sinai discovery tools, (*id.* §§ 5.1-5.6, 6.1-6.2, 7.1-7.3).

75. Neurocrine, in breach of Section 2.1(c) of the License Agreement never sought, or obtained, written consent from Mount Sinai before entering the Neurocrine-AbbVie Agreement in June 2010.

2. Neurocrine Breaches Its Obligation To Provide Annual Development Reports and Refuses To Provide Mount Sinai a Complete Copy of the Neurocrine-AbbVie Agreement

76. Neurocrine continued thereafter to breach its obligation to Mount Sinai to provide progress reports and so it never timely advised Mount Sinai of its transfer of Elagolix, a "Licensed Product" under the License Agreement, as well as all of the other "next generation GnRH antagonists," which also are Licensed Products under the License Agreement, to AbbVie. Finally, in or about March 2012, Neurocrine sent Mount Sinai a document titled "Development Report for the years 2006-2012 to Mount Sinai School of Medicine." Neurocrine for the first time notified Mount Sinai of its agreement with AbbVie, referring to it as a "collaboration

agreement . . . whereby Abbott assumed responsibility for [Neurocrine's] GnRH receptor antagonist program." The "Development Report" further stated that in 2011 AbbVie had initiated a Phase II clinical study of Elagolix, for the treatment of another serious endocrine disorder, uterine fibroids.

77. This report received in March 2012 was deficient in many ways, including but not limited to: its tardiness; its failure to provide a complete written list of Licensed Product drugs identified by year in each of the preceding years; its failure to identify what drug development milestones had been met; and its failure to enclose an unredacted copy of the Neurocrine-AbbVie Agreement so that Mount Sinai could ensure its interests were protected through the Neurocrine agreement with Abbott/AbbVie, for example, protection of Mount Sinai's ability to control the terms of future royalty payments on sales of Licensed Products by licensees or sublicensees under the License Agreement and the ability to audit AbbVie's future sales of such Licensed Products.

78. Mount Sinai requested a full and complete copy of the Neurocrine-AbbVie Agreement. To date, Neurocrine has declined to provide it. Mount Sinai obtained the redacted version of the Neurocrine-AbbVie Agreement that was publicly filed with the SEC.

I. Mount Sinai Has Not Received Any Additional Compensation from Payments Received by Neurocrine from AbbVie as Contemplated by the Parties in the Original License Agreement

79. The right to sublicense is a valuable and important right that a licensee negotiates to obtain, and pays for, typically through a percentage of sublicensing income received from a sublicensee. This is discussed in more detail above in paragraphs 30-36. Typically, as explained above, parties to a license negotiate the terms of the right to sublicense at the time the license is entered. When the parties agree at the time of the original sublicense, a typical percentage of sublicensing income to be paid to the licensor is 25-35% of sublicensing income received by the

licensee. In other license agreements for its GnRH-R technology, Mount Sinai negotiated for the right to receive between 7-35% of sublicensing income. Alternatively, as here, the parties may agree that the licensee may sublicense only with the prior written consent of the licensor and that the terms of any sublicensing right will be determined at the time consent to a sublicense is requested.

80. If Neurocrine had sought Mount Sinai's prior written consent to the sublicense to AbbVie, as required by paragraph 2.1(c) of the License Agreement, the Parties would have negotiated fair and appropriate compensation to Mount Sinai, reflecting the value that the use of its drug-discovery tool had provided, in exchange for Mount Sinai's consent to the sublicense to AbbVie. Neurocrine, by its breach, deprived Mount Sinai of Mount Sinai's right to receive fair and adequate compensation in exchange for granting Neurocrine the right to sublicense.

81. It was common practice during the 1990s, 2000s, and today, for licensors of critical foundational intellectual property, to receive, in addition to a fair share of royalties and drug sales, a substantial percentage of any sublicensing income paid to the licensee (Neurocrine) by the party (AbbVie) that is sublicensed rights to develop and market the drug. As noted above, research institutions such as Mount Sinai typically are paid 25-35% of all sublicensing revenues, in addition to royalties on the sales of FDA-approved, commercialized drugs.

82. As disclosed in its SEC filings, Neurocrine is obligated under the License Agreement to pay Mount Sinai a 1% royalty on net sales of Elagolix as well as on all sales of any other "Licensed Products." Neurocrine Biosciences, Inc., Annual Report (Form 10-K) (Feb. 9, 2015).

83. On information and belief, the Neurocrine-AbbVie Agreement does not provide Mount Sinai the right to audit AbbVie's sales of Licensed Products for purposes of confirming

the amount of royalties owed to Mount Sinai under the License Agreement.

J. AbbVie Announces Positive Phase III Results for Elagolix

84. On January 8, 2015, AbbVie announced positive top-line results from the first of two ongoing Phase III clinical trials being conducted of Elagolix for treatment of endometriosis. Shares of stock in Neurocrine and Neurocrine's total market capitalization rose on the news. Press Release, AbbVie, AbbVie Announces Positive Top-Line results from Phase 3 Study of Investigational Medicine Elagolix in Patients with Endometriosis (Jan. 8, 2015).

85. Most recently, on September 16, 2015, AbbVie announced positive results from a Phase II clinical trial of Elagolix for treatment of uterine fibroids. Press Release, AbbVie, AbbVie Announces Plans To Proceed to Phase 3 Evaluation of Elagolix in Patients with Uterine Fibroids (Sept. 16, 2015).

86. AbbVie is continuing its development of Elagolix for treatment of at least endometriosis and uterine fibroids, with the goal of obtaining FDA approval of Elagolix for both disorders.

87. Under its timeline, AbbVie aims to obtain FDA approval for, and begin marketing of, Elagolix in 2017. Some analysts have predicted AbbVie's annual sales of Elagolix will peak as high as $1.2 billion for endometriosis treatment, with annual peak sales of an additional $1.9 billion for treating uterine fibroids.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Breach of Written Contract)

88. Plaintiff here alleges and incorporates by reference all of the facts alleged in paragraphs 1-87, above.

89. At all relevant times since August 1999, there was a written, valid contract

between Mount Sinai and Neurocrine, titled "Non-Exclusive License Agreement," a true and correct copy of which is attached hereto as Exhibit 1, with the most relevant terms described in more detail in paragraphs 48-57, above.

90. Mount Sinai has performed all of its obligations due and owing under the contract, and has provided Neurocrine all of the bargained-for consideration.

91. Neurocrine has engaged in multiple breaches of the contract. In particular, Neurocrine has repeatedly, including during the past six years, breached Section 3.5 of the License Agreement by: (1) failing to provide, annually, a complete written list of the Licensed Products discovered during each of the previous years using the Licensed Patent Rights; (2) failing to timely provide Development Reports for any of the calendar years 2003-2012 on or before January 1 of each year describing the development status of each Licensed Product in the previous year; (3) failing to provide adequate development reports meeting the requirements of the License Agreement for any of the calendar years 2003-2014; and (4) failing and refusing to provide Mount Sinai a complete and unredacted copy of the June 2010 Neurocrine-AbbVie agreement.

92. Neurocrine also breached the License Agreement in June 2010 when it sublicensed its rights from Mount Sinai to AbbVie, as alleged above in paragraphs 70-74, without seeking, or obtaining, the prior written consent of Mount Sinai as required by Section 2.1(c) of the License Agreement. The Neurocrine-AbbVie Agreement constitutes an unauthorized (i.e., unconsented-to) sublicense in at least three ways. First, Neurocrine effected a sublicense by licensing to AbbVie the rights Mount Sinai had licensed to Neurocrine, namely all rights to research and develop Elagolix and other as-yet unknown, and/or unidentified, follow-on compounds that constitute "Licensed Products" under the License Agreement. Second,

Neurocrine agreed to transfer to AbbVie all technology and assets, related to those compounds and products. Third, the Neurocrine-AbbVie Agreement transferred to AbbVie the right and power to control and direct the use of Mount Sinai's patented discovery tools to research and develop both Elagolix and as-yet unidentified "follow-on" compounds or "next-generation" GnRH antagonists.

93. More specifically, the Neurocrine-AbbVie Agreement: transfers the entirety of Neurocrine's GnRH antagonist program to AbbVie; sets out the terms and conditions on which Neurocrine and AbbVie are to collaborate in connection with the research, development, and commercialization of GnRH antagonist products, referred to as unidentified "Follow-on compounds" (the definition of which is redacted in the publically available version of the Neurocrine-AbbVie Agreement), to be identified and developed using the Mount Sinai drug-discovery tools; and provides AbbVie an exclusive worldwide license "to research, develop, make," and commercialize Elagolix and other GnRH antagonist products identified and developed using the Mount Sinai licensed drug-discovery tools. The Neurocrine-Abbott June 16, 2010, press release (Ex. 2) and Neurocrine's belated development report to Mount Sinai make clear that, through the Neurocrine-AbbVie Agreement, Neurocrine transferred to AbbVie worldwide exclusive rights to research, develop, and commercialize Elagolix and all next-generation GnRH antagonists, and Neurocrine transferred to AbbVie its "GnRH antagonist program." (Ex. 2 (press release); *see also, e.g.*, Ex. 3 (Neurocrine-AbbVie Agreement) §§ 3.1, 6.2, 7.3.) That program consists of research for, and identification, screening, and development of drugs that are "Licensed Products" within the meaning of section 1.5 of the Mount Sinai-Neurocrine License Agreement (Ex. 1). These rights transferred by Neurocrine to AbbVie are exactly those rights that Mount Sinai licensed to Neurocrine, in sections 1.6 and 2.1(a) of the

License Agreement. Neurocrine's sublicensing of these same rights to AbbVie without Mount Sinai's consent is a material breach.

94. Second, the Neurocrine-AbbVie Agreement transfers to AbbVie all technology needed to perform the contemplated research and development work. Neurocrine and AbbVie committed to an "Exclusive Collaborative Effort," i.e., a mutual agreement that neither would compete in, or develop any other, similar drugs. (Ex. 3 § 2.3.) Pursuant thereto, Neurocrine promised to transfer to AbbVie all of its technology used in researching and developing drug candidates. The Neurocrine-AbbVie Agreement requires that "data, information, technology, and assets related to the Compounds and Products. . . shall be transferred to a site selected by Abbott." (*Id*. § 6.1(d).) The terms "Compounds" and "Products" in the Neurocrine-AbbVie Agreement are defined to include those compounds that also count as "Licensed Products" under the Mount Sinai-Neurocrine License Agreement. This provision thus assured that Neurocrine would transfer to AbbVie, and that AbbVie could take over, all of Neurocrine's research tools related to the Compounds and Products, and that AbbVie could duplicate, confirm, and continue all of the drug product research, including not only the continued research, characterization, and development of Elagolix, but also the screening, identification, and development of the unknown "Follow On Compounds" (see *id*. § 1.32), the definition of which is redacted in the publicly available Neurocrine-AbbVie Agreement.

95. Finally, Neurocrine transferred to AbbVie the right and power to take over, and direct and control, from the date the agreement was entered in June 2010, the contemplated drug research, development, and commercialization program. The Neurocrine-AbbVie Agreement provides for a joint research and development program, under which AbbVie is responsible for and assumes sole responsibility for the development of Elagolix, obtaining FDA approval to sell

Elagolix for treatment of at least endometriosis and uterine fibroids, and for research into the identification, discovery, and development of other, "follow-on," or "next-generation," GnRH antagonists, using Mount Sinai's patented drug discovery tools, for treatment of sex-hormone disorders.

96. In particular, Article 5 of the Neurocrine-AbbVie Agreement contemplates a "Collaborative Development Plan," but then commits to AbbVie the "sole responsibility and authority with regard to (a) Development activities related to Products, . . . (b) manufacturing and commercial supply . . . and (c) Commercialization of Products." (Ex. 3 § 5.6.) Neurocrine further transferred to AbbVie control over research, including research using the Mount Sinai discovery tools, by transferring to AbbVie all "Technology and assets related to the Compounds and Products." (*Id.* § 6.1(d).) In addition, AbbVie was granted control of the funding for "Transition" work and thus has the power to direct and dictate what work Neurocrine is to perform. (*Id.* § 6.2.) The agreement also provides for a "collaborative development program," including research into the "next-generation," or "Follow-on" drugs, as well as Elagolix. (*Id.* Art. 7.) Again, AbbVie is provided the power of the purse strings as it funds this research program also. (*Id.* § 7.3.) Neurocrine has thus, implicitly, if not explicitly, sublicensed AbbVie by transferring to AbbVie the power to use Mount Sinai's licensed tools, and/or the power to direct Neurocrine's use of those tools, in the research desired by AbbVie.

97. Pursuant to the Neurocrine-AbbVie Agreement, AbbVie has taken over, conducted, directed, and/or paid Neurocrine to conduct such further drug research and development work. Neurocrine thus ceded to AbbVie control over all further GnRH antagonist drug identification, screening, and development activities, including the development and commercialization of Elagolix, and Neurocrine performed such research and development work

at the direction of AbbVie. Thus, even if Neurocrine and AbbVie attempted to write the "Collaboration Agreement" so as to not expressly sublicense Mount Sinai's patents to AbbVie, Neurocrine's grant to AbbVie of the power to control and direct research into the "Licensed Products" covered by the Mount Sinai-Neurocrine license, including directing Neurocrine to use the Mount Sinai tools in ongoing research or development, constitutes a sublicense.

98. Mount Sinai has suffered damages as a result of Neurocrine's breach of contract, in an amount currently unknown and to be proven at trial. Based on public records, Neurocrine has received to date at least $105 million in sublicensing income and will receive hundreds of millions of dollars more in sublicensing income. As discussed, Mount Sinai is entitled to a substantial percentage of sublicensing income and will suffer hundreds of millions of dollars in damages as a result of Neurocrine's breach. Neurocrine has, through its breach, effectively deprived Mount Sinai of the value of the right to sublicense, which is worth at least 25-35% of all sublicensing revenues. If Neurocrine had properly requested and obtained Mount Sinai's prior written consent to the sublicense to AbbVie, Mount Sinai would have secured at least the following: (1) Neurocrine's agreement to reasonably share with Mount Sinai the $605 million of up-front and milestone sublicensing revenue that AbbVie agreed to pay to take over Elagolix and Neurocrine's GnRH antagonist drug development program; (2) a reasonable share of all sublicensing income that Neurocrine will receive on AbbVie's future sales of Elagolix and other Licensed Products; (3) acceptable terms for the payment of royalties on sales made by AbbVie; and (4) the right to audit AbbVie's sales records to confirm the accuracy and correctness of royalty amounts on all net sales of Licensed Products, including Elagolix.

SECOND CLAIM FOR RELIEF
(Declaratory Relief)

99. Plaintiff here alleges and incorporates by reference all of the facts alleged in

paragraphs 1-98 above.

100. An actual controversy has arisen and now exists between Mount Sinai and Neurocrine concerning their respective rights and duties. Mount Sinai, as specified above, contends Neurocrine breached the License Agreement in June 2010 when it sublicensed its rights from Mount Sinai to AbbVie, as alleged above in paragraphs 70-74, without seeking, or obtaining, the prior written consent of Mount Sinai as required by Section 2.1(c) of the License Agreement. The Neurocrine-AbbVie Agreement constitutes an unauthorized (i.e., unconsented-to) sublicense in at least three ways. First, Neurocrine effected a sublicense by licensing to AbbVie the rights Mount Sinai had licensed to Neurocrine, namely all rights to research and develop Elagolix and other as-yet unknown, and/or unidentified, follow-on compounds that constitute "Licensed Products" under the License Agreement. Second, Neurocrine agreed to transfer to AbbVie all technology and assets related to those compounds and products. Third, the Neurocrine-AbbVie agreement transferred to AbbVie the right and power to control and direct the use of Mount Sinai's patented discovery tools to research and develop both Elagolix and as-yet unidentified "follow-on" compounds or "next-generation" GnRH antagonists.

101. Neurocrine disputes the contentions in the above paragraph.

102. A judicial declaration is necessary and appropriate so that Neurocrine will pay to Mount Sinai a percentage of sublicense income of 35% of all sublicense income payments Neurocrine receives from AbbVie.

PRAYER FOR RELIEF

Plaintiff demands relief as follows:

A. That Plaintiff have and recover damages from Defendant's breach of contract, in an amount to be proven at trial;

B. That Plaintiff receive 35% of Sublicense Income Payments that Neurocrine

receives from AbbVie;

C. That the Court order Defendant to pay to Plaintiff's costs of suit; and

D. That the Court direct such other and further relief as it may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues triable by a jury.

DATED: December 1, 2015

/s/ Honor Costello

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